

## **EXHIBIT L**

Konstantin Walmsley, M.D.

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IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

- - -  
IN RE: ETHICON, INC. : Master File  
PELVIC REPAIR SYSTEM : No.  
PRODUCTS LIABILITY : 2:12-MD-02327  
LITIGATION :  
: MDL NO. 2327  
THIS DOCUMENT RELATES : JOSEPH R. GOODWIN  
TO THE FOLLOWING CASES : U.S. DISTRICT JUDGE  
IN WAVE 2 OF MDL 200: :  
JOANNE PHILLIPS : CASE NO.  
v. : 2:12-cv-02489  
ETHICON, INC., et al. :  
: - - -

August 17, 2016

- - -  
Expert deposition of  
KONSTANTIN WALMSLEY, M.D., taken pursuant  
to notice, was held at Courtyard Marriott  
West Orange, 8 Rooney Circle, West  
Orange, New Jersey, beginning at 12:42  
p.m., on the above date, before Kimberly  
A. Cahill, a Federally Approved  
Registered Merit Reporter and Notary  
Public.

- - -  
GOLKOW TECHNOLOGIES, INC.  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

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19 Johnson and Ethicon

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2

KONSTANTIN WALMSLEY, M.D.,

3

after having been duly sworn, was  
examined and testified as follows:

5

— — —

6

EXAMINATION

7

— — —

8

BY MS. STUBBS:

9 Q. Dr. Walmsley, we've met  
10 before, but again, for the record, my  
11 name is Ashley Stubbs and I'm here on  
12 behalf of Ethicon and Johnson & Johnson.

13 Do you understand that we're  
14 taking your deposition today in the  
15 Joanne Phillips matter?

16 A. I do.

17 Q. And you've been retained by  
18 the Motley Rice firm to render opinions  
19 about the injuries Ms. Phillips is  
20 claiming as a result of the TVT implant;  
21 is that correct?

22 A. That's correct.

23 Q. I just want to make sure I  
24 have an accurate list of the other cases

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1 that you've been deposed in that involve  
2 Ethicon products.

3 A. Certainly.

4 Q. So I was going to run  
5 through those, and tell me if I miss any.

6 A. Okay. Certainly.

7 Q. I have that you were deposed  
8 in June of 2016 in the Martin case?

9 A. Yes, ma'am.

10 Q. And then also that month in  
11 the Bailey case.

12 A. Yes, that's correct.

13 Q. And then same, June 2016, in  
14 the Manor case?

15 A. Yes.

16 Q. And then in the Pridmore  
17 case?

18 A. Yes.

19 Q. Then in the Lindberg case?

20 A. That's correct.

21 Q. It was a general deposition,  
22 I believe?

23 A. Yeah, that's correct.

24 Q. And then the Sherry Fox

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1 matter?

2 A. Yes.

3 Q. And then the Ridgley,

4 R-I-D-G-L-E-Y?

5 A. The Ridgley matter, yes.

6 Q. Ridgley.

7 Barbee or Barbee, were you

8 deposed --

9 A. Barbee, yes, that was just  
10 recently, yes.

11 Q. And then I deposed you in  
12 the McIntyre case; is that correct?

13 A. Yes, ma'am.

14 Q. And then you were also  
15 deposed in the Vanbuskirk case?

16 A. Yes.

17 Q. Javins? Javins?

18 A. Correct.

19 Q. Barr?

20 A. Correct.

21 Q. Garcia?

22 A. Yes.

23 Q. And then were you deposed  
24 last week in the Ward and Baker cases?

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1           A.     Yes.

2           Q.     And then we're here today on  
3     Phillips and I believe you have another  
4     deposition taken in the Birt case; is  
5     that correct?

6           A.     B-I-R-T, yes.

7           Q.     Any other cases that you've  
8     been deposed in involving Ethicon  
9     devices?

10          A.     Yes.

11          Q.     Okay. What are those names?

12          A.     This is a case from 2010,  
13     Gonzalez verse Ethicon. That relates to  
14     a dysfunctional Ethicon stapler that  
15     resulted in complications.

16          Q.     So that wasn't a mesh  
17     device; is that correct?

18          A.     No, ma'am, no.

19          Q.     Any other Ethicon cases that  
20     we haven't discussed?

21          A.     No.

22          Q.     And then you've also served  
23     as an expert witness for the plaintiffs  
24     in other mesh cases involving devices not

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1 manufactured by Ethicon; is that correct?

2 A. Yes.

3 Q. And do those -- who are  
4 those manufacturers?

5 A. Those manufacturers include  
6 Bard, Boston Scientific, AMS. I believe  
7 that's it.

8 Q. And in all of the cases  
9 where you testified or been retained to  
10 render opinions about a synthetic mesh  
11 device, were those cases where you were  
12 retained by the plaintiff?

13 A. In the pelvic mesh-related  
14 arena, yes.

15 Q. And in all of those cases,  
16 was it your opinion that the device  
17 implanted in the plaintiff caused their  
18 injuries?

19 A. To some degree, yes.

20 Q. And in those cases where you  
21 served as an expert in synthetic mesh  
22 device cases, did you also opine in all  
23 of those cases that the warnings were  
24 inadequate?

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1                   A.        No.

2                   Q.        Has there ever been a case  
3        where you said the warnings were  
4       adequate?

5                   A.        No.

6                   Q.        Okay.

7                   A.        There are certain instances  
8       earlier on when I was retained in these  
9       matters that I didn't comment on the IFU.  
10      To my knowledge, I don't recall  
11     commenting on the IFU, for example, in  
12     the Martinez case, which was Martinez  
13     versus AMS in March of 2014.

14                   But certainly over time,  
15     that has become an opinion of mine.

16                   Q.        When you were retained and  
17     asked to render your opinion in any  
18     synthetic mesh case about the IFU, was it  
19     always your opinion that that IFU was  
20     inadequate to warn the physician of the  
21     risk claimed in the case?

22                   A.        In many instances, yes.

23                   Q.        Was there ever a case where  
24     you didn't -- where you were asked to

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1 render an opinion as to the warnings and  
2 didn't render that opinion?

3 A. I mean, the only instance in  
4 which that happened were in cases where I  
5 vetted those cases and felt, on behalf of  
6 the attorneys who asked me to review the  
7 case, that there weren't any issues  
8 related to the mesh product.

9 Q. In all the cases where you  
10 were deposed in, if in any of those cases  
11 you were asked to render an opinion about  
12 the IFU, just in the cases you were  
13 deposed in, was it your opinion that the  
14 IFU was inadequate?

15 A. That would be correct.

16 Q. What did you do to prepare  
17 for your deposition today, Dr. Walmsley?

18 A. I had a brief discussion  
19 with counsel prior to coming in the room.  
20 I refreshed my memory as it relates to my  
21 report and the medical records.

22 I also additionally reviewed  
23 deposition of Dr. Kim and also a report  
24 by a Dr. Shoemaker.

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1 MS. SANTRA: Off the record.

2 - - -

3 (A discussion off the record  
4 occurred.)

5 - - -

6 MS. STUBBS: Back on.

7 BY MS. STUBBS:

8 Q. Doctor, we were discussing  
9 what you did in preparation for your  
10 deposition and off the record, Ms.  
11 Stewart told me that she was going to  
12 send me a link of the documents you  
13 reviewed, so we won't mark that as an  
14 exhibit, but we'll just note for the  
15 record that that's being supplied by  
16 counsel.

17 But if you could, tell me  
18 the documents you reviewed in order to  
19 prepare your report and opinions in this  
20 case.

21 A. Certainly. So my report  
22 came along with a reliance list, which  
23 contains about two and a half pages of  
24 reference articles. There's also

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1     mentions made in the reliance list as to  
2     my reviewing of the current IFU, patient  
3     brochures, applicable depositions, the  
4     list of complaints, if you will, and I  
5     believe some other -- some other -- some  
6     other documents as well.

7                     MS. STUBBS: Okay.

8                     Let me just go ahead and  
9                     mark a few documents as exhibits  
10                    and then we'll be able to look at  
11                    your reliance list together.

12                    THE WITNESS: Certainly.

13                    - - -

14                    (Deposition Exhibit No.  
15                    Walmsley (Phillips)-1, Notice of  
16                    Deposition of Konstantin Walmsley,  
17                    M.D., was marked for  
18                    identification.)

19                    - - -

20     BY MS. STUBBS:

21                    Q.     So, first, I'm going to hand  
22                    you just the deposition notice.

23                    A.     Yes.

24                    Q.     And are you familiar with

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1 this notice?

2 A. I am.

3 Q. And this is what requested  
4 you to appear today in the Phillips case;  
5 correct?

6 A. Yes, ma'am.

7 Q. And as part of that, we  
8 asked you to bring certain documents with  
9 you; is that correct?

10 A. Uh-hum.

11 Q. And off the record, counsel  
12 provided me with the invoice for this  
13 case, for your charges to date, and  
14 there's some other documents we requested  
15 and I'm going to walk through those.

16 But first I want to ask you,  
17 have you reviewed any Ethicon company  
18 documents to date?

19 MS. SANTRA: Object to form.

20 MS. STUBBS: For the  
21 Phillips matter.

22 THE WITNESS: I mean, with  
23 the exception of the TVT IFU and  
24 having seen a brochure, I've not.

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1 BY MS. STUBBS:

2 Q. You haven't reviewed any  
3 internal company e-mails in this matter;  
4 is that correct?

5 MS. SANTRA: Object to form.

6 THE WITNESS: I have not.

7 - - -

8 (Deposition Exhibit No.

9 Walmsley (Phillips)-2, Rule 26  
10 Expert Report of Konstantin  
11 Walmsley, MD, was marked for  
12 identification.)

13 - - -

14 BY MS. STUBBS:

15 Q. I'm going to hand you what I  
16 marked as Exhibit 2 -- it's a copy of  
17 your report -- and just ask you, is that  
18 a correct copy of your report in the  
19 Joanne Phillips matter?

20 A. Yes, it is.

21 Q. And does this report contain  
22 all of your opinions in the Phillips  
23 case?

24 A. Yes, it does.

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1

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2

(Deposition Exhibit No.

3

Walmsley (Phillips)-3, 11/20/15

4

Curriculum Vitae of Konstantin

5

Walmsley, was marked for

6

identification.)

7

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8

BY MS. STUBBS:

9

Q. Then I'm going to hand you  
what I marked as Exhibit 3 and just ask  
you to verify that this is an updated  
copy of your C.V.

13

A. Yes.

14

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15

(Deposition Exhibit No.

16

Walmsley (Phillips)-4, Document

17

Entitled "Materials Reviewed", was

18

marked for identification.)

19

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20

BY MS. STUBBS:

21

Q. And then as Exhibit 4, is  
this the reliance list that you referred  
to earlier as far as the materials  
reviewed in formulating your opinions in

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1 the Phillips case?

2 A. That's correct.

3 Q. And so then let's look at  
4 Exhibit 4, the materials reviewed. It  
5 states that you looked at depositions of  
6 medical providers. Is that the  
7 deposition of Dr. Kim?

8 A. Yes.

9 Q. Did you review any other  
10 depositions of any other treaters in this  
11 case?

12 A. I did not.

13 Q. Did you also review the  
14 deposition testimony of the plaintiff?

15 A. I did.

16 Q. And then medical and billing  
17 records, did you review all medical  
18 records provided to you by counsel in  
19 this case?

20 A. I did.

21 Q. Have you reviewed any  
22 additional records since drafting your  
23 report?

24 A. The only other additional

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1 record that I reviewed in her behalf was  
2 a expert report by a Dr. Shoemaker.

3 Hayleigh, did you send me  
4 additional records on her? I don't quite  
5 recollect seeing them. I just -- that's  
6 why I'm checking.

7 MS. STUBBS: Oh, please.

8 Thank you.

9 THE WITNESS: Yeah, yeah.

10 BY MS. STUBBS:

11 Q. And when you refer to Dr.  
12 Shoemaker, that's the expert on behalf of  
13 Ethicon; is that correct?

14 A. That's correct.

15 Q. And did his report in any  
16 way change any of your opinions in your  
17 report that was served?

18 A. No, ma'am.

19 MS. STUBBS: Hayleigh, while  
20 you look for that, I'm just going  
21 to keep going.

22 MS. SANTRA: Sure. That's  
23 fine.

24 BY MS. STUBBS:

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1                   Q.     Next, you list instructions  
2     for use. Did you review the TVT IFU that  
3     was in place in January of 2005 when Ms.  
4     Phillips had her implant?

5                   A.     I did.

6                   Q.     And did you review any other  
7     TVT IFUs?

8                   A.     Specific to this case, no,  
9     but I have a whole dossier of IFUs.

10                  Q.     But as far as your opinions  
11    in this case regarding the warnings, do  
12    they pertain solely to the IFU in place  
13    at the time of Ms. Phillips' implant?

14                  A.     Yes.

15                  Q.     And then you also list the  
16    patient brochure. Is that the patient  
17    brochure that was in use in January of  
18    2005?

19                  A.     Correct.

20                  Q.     Do you have any opinions  
21    about the adequacy of the patient  
22    brochure in this matter?

23                  A.     I don't.

24                  Q.     Then you also reviewed the

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1 plaintiff fact sheet; is that correct?

2 A. Yes, I did.

3 Q. And then you list numerous  
4 articles that you reviewed. Anything  
5 else that's not contained in this  
6 reliance list that you reviewed in this  
7 matter?

8 A. No.

9 - - -

10 (Deposition Exhibit No.

11 Walmsley (Phillips)-5, 6/17/16  
12 Encounter Summary for Joanne  
13 Phillips, was marked for  
14 identification.)

15 - - -

16 BY MS. STUBBS:

17 Q. I'm going to show you next  
18 what I've marked as Exhibit 5. This is  
19 what we have as your IME record for Ms.  
20 Phillips.

21 Did you take any notes  
22 during the IME or is everything reflected  
23 in this document that pertains to Ms.  
24 Phillips' IME?

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1                   A.     I did not take any notes.

2     Really everything that I documented and  
3     recorded during my IME is present in the  
4     report.

5                   Q.     When you say report, are you  
6     referring to the IME or the expert  
7     report?

8                   A.     The IME.

9                   Q.     And we'll walk through that  
10    in further detail later, but it is your  
11    testimony today that any information  
12    taken down by you would be contained --  
13    during the IME would be contained in that  
14    document; is that correct?

15                  A.     Yes.

16                    - - -

17                  (Deposition Exhibit No.

18                  Walmsley (Phillips)-6, Invoice for  
19                  Phillips Case Review, was marked  
20                  for identification.)

21                    - - -

22    BY MS. STUBBS:

23                  Q.     And then I'm going to show  
24     you what I've marked as Exhibit 6. This

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1 is the invoice that counsel provided us  
2 with before the deposition began for your  
3 fees in the Phillips case.

4 Can you tell me for the  
5 record how much you've been paid in this  
6 case?

7 A. \$5,575.

8 Q. And what do those charges  
9 include?

10 A. They include the review of  
11 the medical records and depositions, as  
12 well as the preparation of the report.

13 Q. Do you recall when you were  
14 first retained in this case?

15 A. It would have been in the  
16 latter part of May to early June.

17 Q. Of this year?

18 A. 2016, yes.

19 Q. And how long did it take you  
20 to formulate your opinions in this case?

21 A. Roughly eight to nine hours.

22 Q. And your opinions were based  
23 on the review of the documents we've  
24 discussed?

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1 A. In part, yes.

2 Q. And then also of your  
3 physical exam of the plaintiff?

4 A. And my IME, yes.

5 Q. Have you spoken with any of  
6 Ms. Phillips' treating physicians?

7 A. No.

8 Q. And on how many occasions  
9 have you met Ms. Phillips?

10 A. Only once.

11 Q. And was that during the IME?

12 A. Yes.

13 Q. What is your hourly rate?

14 A. \$500 an hour.

15 Q. And does that include -- is  
16 that a flat rate for any of your work or  
17 is there a different rate for testimony,  
18 for example?

19 A. It's more or less the same.

20 For out-of-town court appearances where a  
21 full day is taken, it's a  
22 five-thousand-dollar rate unless the time  
23 spent exceeds eight hours.

24 Q. Did you personally draft

Konstantin Walmsley, M.D.

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1 your report in this matter?

2 A. I did.

3 Q. Doctor, I believe that  
4 defense expert Dr. Shoemaker at the time  
5 of issuing the report hadn't conducted an  
6 IME yet, but I know that that is in the  
7 works -- Hayleigh, I'm not sure when  
8 that's scheduled -- but is that something  
9 that you would want to review and  
10 consider whether or not you need to  
11 supplement your opinions based on that if  
12 an IME is done?

13 A. Certainly, yes.

14 Q. Before we get into your  
15 opinions in this case and the IME, I'd  
16 like to talk to you a little bit about  
17 the condition that Ms. Phillips had with  
18 regard to incontinence.

19 In your practice, what  
20 percentage of your practice is dedicated  
21 to treating women with incontinence?

22 A. Probably 20 percent. It's a  
23 guess.

24 Q. And would that include women

Konstantin Walmsley, M.D.

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1 with stress urinary incontinence as well  
2 as urge incontinence?

3 A. Yes.

4 Q. And would you agree that the  
5 device TVT is indicated to treat stress,  
6 not urge, incontinence?

7 A. That's correct.

8 Q. And would you agree that Ms.  
9 Phillips had mixed incontinence, meaning  
10 a stress component and an urge component?

11 A. You're talking about at the  
12 time of her initial implant?

13 Q. At the time of her implant,  
14 yes.

15 A. She had mixed urinary  
16 incontinence.

17 Q. Would you agree that stress  
18 and urge incontinence greatly affect a  
19 woman's quality of life?

20 A. Yes.

21 Q. And would you agree that a  
22 surgery using a mesh device to treat SUI  
23 is an elective procedure?

24 A. Yes.

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1                   Q.     It's not a life-threatening  
2 condition.

3                   A.     Only quality of  
4 life-threatening, as I often talk to  
5 patients about.

6                   Q.     How do you see in your  
7 practice incontinence affect your  
8 patients' lives?

9                   A.     Well, it's well-known that  
10 incontinence is a quality-of-life  
11 condition and there have been numerous  
12 studies looking at quality of life in  
13 women with incontinence.

14                   And there's no question that  
15 it affects quality of life in multiple  
16 ways, not only because of the condition  
17 itself and the fact that having  
18 incontinence can increase risk of skin  
19 breakdown, urinary tract infections, but  
20 it also has social and psychological  
21 impacts, for example, maybe not being  
22 involved or active in the same things you  
23 might have been before, whether it be  
24 exercise or certain social situations,

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1 wearing black, for example, to kind of  
2 hide incontinence.

3 There have been studies that  
4 have correlated depression with urinary  
5 incontinence, so it's certainly impactful  
6 on multiple levels.

7 Q. Would you agree that it's  
8 important to have both surgical and  
9 nonsurgical treatment options available  
10 to women for the treatment of  
11 incontinence?

12 A. Yes.

13 Q. And would you agree that  
14 there are risks associated with any  
15 surgical treatment of stress urinary  
16 incontinence, whether that is with or  
17 without mesh?

18 A. Yes.

19 Q. Would you agree that the  
20 risk of scar formation -- scar tissue  
21 formation -- is a risk associated with  
22 any surgery to treat SUI whether that's  
23 with or without mesh?

24 A. Not completely, but in part,

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1 yes.

2 Q. What part do you disagree  
3 with?

4 A. Any surgery can create  
5 scarring; however, surgery involving the  
6 use of pelvic mesh creates a greater  
7 degree of scarring.

8 Q. I know one of your opinions  
9 -- and we'll get into it in further  
10 detail -- is regarding alternative  
11 treatment options as opposed to using a  
12 mid-urethral sling like TVT; is that  
13 correct?

14 A. Correct.

15 Q. And you propose using a  
16 fascial sling; is that correct?

17 A. An autologous fascial sling,  
18 yes.

19 Q. And that's where actual  
20 human tissue is used to repair or to  
21 treat stress urinary incontinence; is  
22 that correct?

23 A. That's an instance where  
24 instead of creating the support to the

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1      urethra with a synthetic piece of  
2      polypropylene mesh, one actually uses  
3      what's called fascia, which is a  
4      connective tissue layer that can mimic or  
5      provide a similar support.

6            Q.      And would you agree that  
7      that alternative procedure does not  
8      involve the use of a medical device?

9            MS. SANTRA:   Object to form.

10           THE WITNESS:   Correct.

11           Other than suture material to  
12          suture the sling in place, that  
13          would be correct.

14          BY MS. STUBBS:

15           Q.      And that's because you're  
16          using the actual tissue to provide  
17          support; correct?

18           A.      Yes.

19           Q.      And would you agree that  
20          there are risks associated with that  
21          procedure?

22           A.      I would.

23           Q.      And would you agree that  
24          that is a longer operating time?

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1 A. This is true.

2 Q. And does that risk -- does  
3 that surgery, using human tissue as  
4 opposed to a polypropylene-based mesh,  
5 does that surgery present the risk of  
6 scar formation?

7 A. Yeah.

8 Q. Can that surgery result in  
9 dyspareunia?

10 MS. SANTRA: Object to form.

11 THE WITNESS: To some  
12 degree, yes.

13 BY MS. STUBBS:

14 Q. Can that surgery result in  
15 pelvic pain?

16 A. Once again, to some degree,  
17 yes.

18 Q. Currently, you said 20  
19 percent of your practice is dedicated to  
20 treating women with incontinence; is that  
21 correct?

22 A. That's correct.

23 Q. Of those patients that you  
24 treat, how many of them would you say,

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1 percentage-wise, do you ultimately  
2 perform surgery on?

3 A. Probably about 20 to 30  
4 percent.

5 Q. And when you don't perform a  
6 procedure to treat the incontinence, are  
7 you using medication?

8 A. Typically, medications or  
9 lifestyle/behavioral modifications, in  
10 addition to physical therapy.

11 Q. And in this particular case,  
12 Ms. Phillips, before having the TVT  
13 implant, she tried alternative forms of  
14 therapy including Detrol LA; is that  
15 correct?

16 A. She did try medications for  
17 her condition, yes.

18 Q. And based on the records I  
19 reviewed, it looked like the Detrol was  
20 actually helping; is that correct?

21 A. It was helping with her  
22 urgency and urgency urinary incontinence,  
23 yes.

24 Q. But not the stress; is that

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1 correct?

2 A. That's correct.

3 Q. And, ultimately, she elected  
4 to go forward with the TVT procedure to  
5 treat her stress incontinence; correct?

6 A. Yes.

7 Q. And the Detrol to your --  
8 strike that.

9 Based on your review of the  
10 records, did the Detrol have any impact  
11 on her stress incontinence?

12 A. Not that I could conclude  
13 from my evaluation of the records, no.

14 Q. Do you disagree with Dr.  
15 Kim's decision in any way to implant TVT  
16 in Ms. Phillips in 2005?

17 A. I do not.

18 Q. Do you agree that she was an  
19 appropriate candidate for that device  
20 based on her presentation of symptoms in  
21 January 2005?

22 A. I do.

23 Q. Going back to your opinion  
24 regarding alternative forms of treatment

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1 and, instead of using a sling or a  
2 polypropylene-based sling, using human  
3 tissue to repair it, would you agree that  
4 that surgery using human tissue also  
5 presents the risk of recurrence of  
6 urinary problems?

7 A. Yes.

8 Q. Does it present the risk of  
9 infection?

10 A. Yes.

11 Q. Do you agree that  
12 mid-urethral slings are a -- within the  
13 standard of care currently for the  
14 treatment of stress urinary incontinence?

15 A. Yes.

16 Q. Do you currently implant any  
17 mid-urethral slings as a treatment option  
18 for your patients suffering from stress  
19 urinary incontinence?

20 A. I do.

21 Q. And is that -- what device  
22 is that that you use?

23 A. I'm using the Coloplast ARIS  
24 device.

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1                   Q.     And is that a  
2 polypropylene-based sling?

3                   A.     It is.

4                   Q.     And you would agree that TVT  
5 is a polypropylene-based sling; correct?

6                   A.     Yes.

7                   Q.     Why do you choose to use the  
8 sling you use as opposed to TVT?

9                   A.     A lot of times when we  
10 examine devices and kits, obviously  
11 besides an analysis of related  
12 literature, discussions with key opinion  
13 leaders, to a large degree, the -- you  
14 can get a lot of information from  
15 palpating and examining mesh.

16                   One of the issues that I  
17 find appealing about the Coloplast sling  
18 is, it tends to have less elasticity, so  
19 as a result, the rate of contraction is  
20 less, which essentially means when I  
21 place the sling, I don't have to  
22 necessarily be concerned as much about  
23 the way that sling will change over time  
24 as it relates to contraction.

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1 Q. Okay.

2 A. So I'm still placing the  
3 sling in a tension-free fashion, but I'm  
4 less concerned about how the contraction  
5 of the sling will affect patients'  
6 voiding function long term.

7 Q. Did you see any evidence of  
8 contraction of Ms. Phillips' sling when  
9 you examined her?

10 A. I did not.

11 MS. STUBBS: Doctor, I know  
12 we've walked through this position  
13 statement in other cases, so I'm  
14 not going to go through it in any  
15 great detail, but I want to show  
16 you what I've marked as Exhibit 7,  
17 the AUGS and SUFU position  
18 statement that was updated in  
19 2016.

20 - - -

21 (Deposition Exhibit No.  
22 Walmsley (Phillips)-7, 6/16 AUGS  
23 and SUFU Position Statement, was  
24 marked for identification.)

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1 - - -

2 BY MS. STUBBS:

3 Q. Are you familiar with this  
4 position statement?

5 A. I am.

6 Q. Are you a member of AUGS or  
7 SUFU?

8 A. I'm not.

9 Q. Would you agree that those  
10 are reputable medical organizations?

11 A. I'm not very in tune with  
12 the specific nature of these  
13 organizations. That being said, I have  
14 colleagues who are good doctors who are  
15 members of the organizations, so I would  
16 have to conjecture that they would be  
17 reputable organizations.

18 Q. And are you not a member of  
19 these organizations because you're not a  
20 urogynecologist?

21 A. No.

22 Q. Okay.

23 A. The AUGS society is geared  
24 towards urogynecologists, but the SUFU

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1 society is open to urogynecologists as  
2 well as physicians such as myself who  
3 have received fellowship training in  
4 female urology.

5 Q. And why are you not a member  
6 of that organization?

7 A. You know, I'm so busy  
8 clinically that joining the organization  
9 has never been something that has been  
10 compelling or meaningful to me, not to  
11 say that I wouldn't appreciate the  
12 opportunity to be a member, but it's just  
13 never, you know, appealed to me just  
14 because I'm so busy clinically as it is.

15 Q. If you would look with me,  
16 this position statement that I've marked  
17 as Exhibit 7 discusses the use of  
18 mid-urethral slings for stress urinary  
19 incontinence; correct?

20 A. Yes.

21 Q. Would you turn with me to  
22 the second page and the point number 3?  
23 In bold, it states: "Polypropylene mesh  
24 mid-urethral slings are a standard of

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1 care for the surgical treatment of SUI  
2 and represent a great advance in the  
3 treatment of this condition for our  
4 patients."

5 Did I read that correctly?

6 A. You did.

7 Q. Do you disagree with that  
8 statement?

9 MS. SANTRA: Object to form.

10 THE WITNESS: The only, you  
11 know, adjective I would disagree  
12 with is "great." I think it's  
13 obviously an advance in the  
14 treatment of this condition. It  
15 has advantages, but it also has  
16 disadvantages.

17 And, I mean, I think to be  
18 fair, if we try to identify  
19 reasons for this statement being  
20 put forth, you know, in part, the  
21 position statement has been put  
22 forth because the use of slings,  
23 there has been some controversy  
24 created obviously with the current

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1                   environment that we're in  
2                   regarding slings.

3                   So inasmuch as I think it's  
4                   an advance, I would argue the  
5                   point that it's a great advance  
6                   simply because I think there are  
7                   pros and cons to using slings.

8                   Certainly if you compare the  
9                   use of polypropylene slings for  
10                   stress urinary incontinence, it's  
11                   still used, perhaps not as  
12                   commonly as it was three or four  
13                   years ago, for example, but it's  
14                   still used, which I think is  
15                   reflective of the fact that  
16                   there's an advance.

17                  BY MS. STUBBS:

18                  Q.     Would you agree that in the  
19                  past three or four years, the litigation  
20                  environment surrounding the pelvic mesh  
21                  products, in particular the mid-urethral  
22                  slings, has had an effect on doctors  
23                  using those devices?

24                  MS. SANTRA: Object to form.

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1                   THE WITNESS: Well, I would  
2                   expand the answer pool to say it's  
3                   both affected doctors and  
4                   patients, but yes.

5 BY MS. STUBBS:

6                   Q.     Do you agree that -- you  
7                   said there are advantages and  
8                   disadvantages to using a mid-urethral  
9                   sling; correct?

10                  A.     Yes.

11                  Q.     Would you agree that there  
12                  are disadvantages as well as advantages  
13                  to using -- to any surgical treatment to  
14                  treat SUI?

15                  A.     I think that's fair, yes.

16                  Q.     In that same section,  
17                  section 3, if you go down a few lines,  
18                  the sentence starting "MUS is associated"  
19                  --

20                  A.     Uh-hum.

21                  Q.     -- it says, "MUS is  
22                  associated with less pain, shorter  
23                  hospitalization, faster return to usual  
24                  activities, and reduced costs as compared

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1 to historic options that have been used  
2 to treat SUI over the past century."

3 Did I read that correctly?

4 A. You did.

5 Q. Do you disagree or agree  
6 with that statement?

7 A. I would agree with every  
8 single comment made there, but I'm not as  
9 privy to the reduced costs analysis. And  
10 the reason I'm not is because the slings  
11 and the devices carry costs. The fact  
12 that patients are not in the hospital as  
13 long would diminish costs. Complication  
14 rates probably would create costs.

15 So I'm not privy to the  
16 analysis that points out reduced costs.

17 Q. But other than that  
18 statement -- that portion of the  
19 statement, you agree with the statement  
20 that I just read?

21 A. This is true.

22 Q. I'd like to go to your  
23 report and let's discuss opinion number  
24 1. And this opinion is regarding the IFU

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1 in place at the time of Ms. Phillips'  
2 implant; correct?

3 A. Yes.

4 Q. And it is your opinion that  
5 the IFU in place in January of 2005 was  
6 not sufficient to enable informed consent  
7 of Ms. Phillips; is that correct?

8 A. Yes.

9 Q. What do you contend should  
10 have been in the IFU that wasn't?

11 A. Well, firstly --

12 MS. SANTRA: Object to the  
13 form.

14 THE WITNESS: -- there's  
15 terminology in the IFU that would  
16 indicate a clinician to believe  
17 that the response to pelvic mesh  
18 is a temporary response.

19 And I quote from one of the  
20 adverse reaction statements from  
21 the IFU in 2005, quote:

22 Transitory local irritation at the  
23 wound site and a transitory  
24 foreign body response may occur.

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1           This response could result in  
2           extrusion, erosion, fistula  
3           formation and inflammation,  
4           unquote.

5           Quite frankly, I think  
6           that's a misleading statement  
7           because those words imply  
8           temporary and we know that the  
9           reaction to mesh, the foreign body  
10           reaction, the inflammatory  
11           response, is a chronic one.

12           And in addition, there are  
13           additional adverse reactions  
14           and/or risks within the use of  
15           suburethral slings that aren't  
16           mentioned in the IFU, for example,  
17           pelvic pain and dyspareunia.

18           And what's important to know  
19           is that inasmuch as  
20           antiincontinence procedures for  
21           SUI can create these potential  
22           complications, the nature of them  
23           is different. For example,  
24           dyspareunia can be much more

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1                   difficult to manage in the  
2                   mesh-based mid-urethral sling  
3                   setting than, for example, in an  
4                   autologous fascial sling.

5                   So besides, for example,  
6                   pelvic pain and dyspareunia, it's  
7                   not only the provision of those  
8                   potential adverse events; it's the  
9                   fact that there's no language or  
10                  context to those potential adverse  
11                  events that speaks to the  
12                  difficulty unique to those adverse  
13                  events in the mesh arena.

14          BY MS. STUBBS:

15          Q.        Let's start with your first  
16          opinion regarding the transitory response  
17          language.

18          A.        Okay.

19          Q.        Did you see any evidence  
20          when you examined Ms. Phillips of a  
21          chronic inflammatory response or foreign  
22          body response?

23                   MS. SANTRA: Object to form.

24                   THE WITNESS: Well, I think

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1           that's a difficult question to  
2           answer because, to be fair, those  
3           specific descriptive terms that  
4           we've just been using are really  
5           histopathological types of terms.

6           What you can appreciate and  
7           what I did appreciate on Ms.

8           Phillips' exam is the presence of  
9           a scar plate and tenderness  
10          related to my exam. Those are  
11          reflective of an inflammatory  
12          process.

13          But to be fair, those  
14          terminologies are probably more  
15          aptly used in a histopathological  
16          type of context.

17          BY MS. STUBBS:

18          Q.     Would you agree that in  
19          order to render an opinion to a  
20          reasonable degree of medical certainty  
21          that Ms. Phillips had a chronic  
22          inflammatory response, you would need  
23          pathology?

24          MS. SANTRA: Object to form.

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1 THE WITNESS: Not  
2 necessarily, because certainly on  
3 clinical exam, if one appreciates  
4 indurated and/or scarred tissue,  
5 for example, around a mesh sling,  
6 especially in the presence of  
7 tenderness, in most often -- in  
8 most instances, within a  
9 reasonable degree of medical  
10 certainty, that defines or  
11 supports the presence of an  
12 inflammatory response.

13 BY MS. STUBBS:

14 Q. Would you agree that an  
15 inflammatory response is a known risk of  
16 implanting any device in the pelvic  
17 space?

18 MS. SANTRA: Object to form.

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1 example, the response is a  
2 self-limited one. There is an  
3 inflammatory response. There  
4 obviously is some degree of  
5 scarring, as there is with any  
6 surgery, but the extent of that  
7 response is significantly  
8 different and short term.

9 BY MS. STUBBS:

10 Q. You also mentioned pelvic  
11 pain and dyspareunia being risks that  
12 were not contained in the IFU at the time  
13 of Ms. Phillips' implant; correct?

14 A. Yes.

15 Q. Ms. Phillips had her implant  
16 in 2005; correct?

17 A. Yes.

18 Q. And based on your review of  
19 the records, are you aware that she  
20 didn't go back to her implanting  
21 physician for nearly eight years after  
22 having that implant?

23 A. That's correct.

24 Q. And she hasn't had a pelvic

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1 exam since 2005 other than your exam; is  
2 that correct?

3 A. Yes.

4 Q. In fact, her doctor, Dr.  
5 Kim, suggested that she have a pelvic  
6 exam and she refused; is that correct?

7 A. Yes.

8 Q. And so to date, you're the  
9 only doctor that has performed a pelvic  
10 exam on Ms. Phillips since she had the  
11 implant; correct?

12 A. Yes.

13 Q. And when I deposed Ms.  
14 Phillips, she represented to me that she  
15 had dyspareunia post-implant on one  
16 occasion. Did you see that in the  
17 deposition?

18 A. I did.

19 Q. Have you seen anywhere in  
20 the medical records where she complained  
21 of dyspareunia post-implant on numerous  
22 occasions?

23 MS. SANTRA: Object to form.

24 THE WITNESS: I did not see

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1                   much reference to dyspareunia at  
2                   all, so I would have to answer  
3                   that question no.

4    BY MS. STUBBS:

5                   Q.     Did you see anywhere in the  
6                   medical records post-implant where Ms.  
7                   Phillips complained of pelvic pain?

8                   MS. SANTRA:   Object to form.

9                   THE WITNESS:   To some  
10                   degree, yes.

11    BY MS. STUBBS:

12                   Q.     Is that when she went to her  
13                   primary care doctor?

14                   A.     Well, I'm thinking about her  
15                   visit to Dr. Kim in 2012. I mean,  
16                   obviously, she came to see him requesting  
17                   the TVT device be removed. Although the  
18                   subject of pain wasn't answered or  
19                   explored, per se, she explained this  
20                   condition where she would be getting red  
21                   bumps, which to my mind is a presentation  
22                   of pain. I concluded that when she was  
23                   saying that, she was speaking about  
24                   pelvic pain. Now, I may not be correct

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1 in that, but that was my conclusion.

2 Q. Were the words "pelvic pain"  
3 referenced in that visit at all?

4 A. Not to my recollection, no.

5 Q. And you familiarized  
6 yourself with Dr. Kim's testimony in this  
7 case; correct?

8 A. Yes.

9 Q. And are you aware that Dr.  
10 Kim testified that if the words "pelvic  
11 pain" or "dyspareunia" had been added to  
12 the IFU in 2005, it wouldn't have changed  
13 his decision to recommend TVT to this  
14 plaintiff?

15 MS. SANTRA: Object to form.

16 THE WITNESS: I recall that.

17 BY MS. STUBBS:

18 Q. Would you agree that the  
19 instructions for use or the IFU for a  
20 product is only one source of risk  
21 information available to a doctor?

22 A. I think it can be one of  
23 several sources, yes.

24 Q. Would you agree that doctors

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1      rely on other sources of information when  
2      gathering information about a product and  
3      whether or not to use that product?

4              A.      Yes.

5              Q.      Do you personally, prior to  
6      using a product, only rely on the IFU to  
7      gain your risk information?

8              A.      I rely heavily on the IFU.

9              Q.      Do you rely on medical  
10     literature?

11             A.      I do.

12             Q.      Do you rely on information  
13     gathered through continuing medical  
14     education seminars?

15             A.      I do.

16             Q.      Do you rely on information  
17     discussed by your colleagues that use the  
18     device?

19             A.      Depending upon the  
20     colleague, yes.

21             Q.      Your second opinion, we've  
22     talked briefly about, but that is the  
23     alternative treatment that you are  
24     proposing to Ms. Phillips. As opposed to

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1 having a TVT, you propose a fascial  
2 sling; is that correct?

3 A. Yes.

4 Q. And you agreed earlier that  
5 that is not an alternative device;  
6 correct? That's using human tissue?

7 MS. SANTRA: Object to form.

8 THE WITNESS: Could you  
9 repeat the question? I'm sorry.

10 MS. STUBBS: Sure.

11 BY MS. STUBBS:

12 Q. You would agree that that  
13 alternative that you proposed does not  
14 involve an alternative medical device.

15 A. No, it doesn't.

16 Q. It's a procedure; is that  
17 correct?

18 A. Correct, yeah.

19 Q. Have you seen anywhere in  
20 Ms. Phillips' records where any treating  
21 physician has recommended that she have  
22 her TVT taken out?

23 A. No.

24 Q. And based on her deposition,

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1 are you aware that she does not currently  
2 have any treating physicians for her GYN  
3 symptoms that she's complaining of?

4 A. Correct.

5 Q. And would you agree that no  
6 doctor, in the medical records or Dr. Kim  
7 in his deposition testimony, has opined  
8 that the TVT device is in fact causing  
9 the symptoms she's complaining of in this  
10 lawsuit?

11 A. Correct.

12 Q. So one of your opinions, I  
13 believe it's your last opinion, is that  
14 she has a guarded prognosis; is that  
15 correct?

16 A. Correct.

17 Q. What is your basis for that  
18 opinion?

19 A. My basis for that opinion  
20 stands on not only my review of the  
21 medical records, depositions, but also on  
22 my independent medical exam.

23 Q. Is it your recommendation  
24 that Ms. Phillips have the TVT explanted?

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1                   A.     Possibly, yes.

2                   Q.     And what is your basis for  
3     that?

4                   A.     Well, she currently has  
5     pelvic pain. She currently has  
6     dyspareunia, although she's only  
7     attempted intimacy once since her sling  
8     was placed.

9                   There are other factors that  
10    are contributing to her pelvic pain that  
11    likely should be treated first in my  
12    opinion --

13                  Q.     What are those factors?

14                  A.     Well, she has what I believe  
15    is lichen sclerosus on the basis of some  
16    inflammation on the posterior wall of her  
17    vaginal space. In addition, she does  
18    have some mild vulvovaginal atrophy. I  
19    would recommend treating those  
20    conditions, you know, in addition to  
21    considering sling removal.

22                  But if I can choose between  
23    performing a procedure or trying  
24    something medical or conservative, I'd

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1   probably opt on the medical/conservative  
2   treatments first.

3           Q.    And the lichen sclerosus and  
4   the vaginal atrophy, are you contending  
5   that those were caused by the mesh at  
6   all?

7           A.    I'm not.

8           Q.    You also have the opinion  
9   that Ms. Phillips has scar plate  
10   formation as a result of the TVT; is that  
11   correct?

12          A.    Yes.

13          Q.    When you examined Ms.  
14   Phillips, did you see any evidence of any  
15   erosion or extrusion of the mesh?

16          A.    I did not.

17          Q.    Have you seen anywhere in  
18   the medical records where any doctor has  
19   seen any erosion or extrusion of the  
20   mesh?

21          A.    No.

22          Q.    When you state that there  
23   was scar plate formation, describe for me  
24   what you were able to palpate or see.

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1                   A.     So, visually, the tissue  
2     around the sling appeared to be somewhat  
3     thicker. On palpation, I could palpate  
4     the ridge of scar tissue around the  
5     sling. There was tenderness in the area  
6     of the sling as I was examining this scar  
7     tissue. There was no specific areas of  
8     point tenderness.

9                   Sometimes, in prior  
10  examinations or with prior patients, they  
11  might have areas that are more tender,  
12  for example, up at the vaginal sulci  
13  which are the upper corners of the  
14  vaginal space. Ms. Phillips did not have  
15  those findings.

16                  Q.     Ms. Phillips had had a  
17  hysterectomy prior to having the TVT; is  
18  that correct?

19                  A.     Yes.

20                  Q.     Would you agree that having  
21  that type of surgery can also result in  
22  scar formation?

23                  MS. SANTRA: Object to form.

24                  THE WITNESS: Possibly, yes.

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1 BY MS. STUBBS:

2 Q. Can it result in pelvic  
3 pain?

4 A. Sometimes it can, yes.

5 Q. Can it result in  
6 dyspareunia?

7 A. Yes.

8 Q. Ms. Phillips' TVT hasn't  
9 been taken out in -- any portion of it;  
10 correct? It's still intact in her body;  
11 correct?

12 A. Yes.

13 Q. And so there's no pathology  
14 in this case; is that correct?

15 A. There's not.

16 Q. And would you agree that  
17 pathology would be necessary in order to  
18 render an opinion to a reasonable degree  
19 of medical certainty that the mesh in her  
20 body had degraded?

21 A. For that particular finding,  
22 yes.

23 Q. So did you see any evidence  
24 of degradation?

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1 A. I did not.

2 Q. Did you see any evidence of  
3 roping, curling, or fraying of the mesh  
4 in Ms. Phillips?

5 A. I did not.

6 Q. Did you see any evidence of  
7 shrinkage or contracture?

8 MS. SANTRA: Object to form.

9 THE WITNESS: Of the mesh,  
10 you mean.

11 MS. STUBBS: Yes. I'm  
12 sorry.

13 THE WITNESS: I did not.

14 BY MS. STUBBS:

15 Q. Did you see any evidence of  
16 particle loss of the mesh in her body?

17 A. I did not.

18 Q. Did you see any evidence of  
19 inadequate tissue ingrowth?

20 A. I did not.

21 Q. Did you see any evidence of  
22 nerve entrapment?

23 MS. SANTRA: Object to form.

24 THE WITNESS: I did not.

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1 BY MS. STUBBS:

2 Q. I'd like to talk with you  
3 now about Ms. Phillips' prior medical  
4 history before having the TVT implanted  
5 and then we'll talk about the actual  
6 implant itself.

7 Would you agree that Ms.  
8 Phillips suffered from back and hip pain  
9 as a result of a motor vehicle accident  
10 she had in the '90s and that pain  
11 continued into the 2000's?

12 A. Yes.

13 Q. And after she had the  
14 implant, she continued to see her primary  
15 care doctor for pain related -- relating  
16 back to that accident.

17 A. That's correct.

18 Q. Would you agree that she had  
19 poorly controlled diabetes prior to  
20 having the TVT implanted?

21 A. I mean, to some degree.

22 Q. And that worsened over time?

23 A. I think it's hard to really  
24 track whether her diabetes was well

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1 controlled or poorly controlled because I  
2 don't -- didn't recall seeing in her  
3 medical records blood tests such as  
4 hemoglobin A1Cs that would otherwise  
5 point towards poorly controlled diabetes,  
6 although there was mention made of poor  
7 diabetic control by her primary care  
8 doctor, Dr. Narula.

9 Q. Would you agree that Dr.  
10 Narula's records reflect that Ms.  
11 Phillips failed to comply on numerous  
12 occasions with doctors' recommendations  
13 regarding her care and treatment of her  
14 diabetes?

15 MS. SANTRA: Object to form.

16 THE WITNESS: Comments to  
17 that effect were made, yes.

18 BY MS. STUBBS:

19 Q. Ms. Phillips was also a  
20 smoker; is that correct?

21 A. Yes.

22 Q. Would you agree that smoking  
23 can impact wound healing following  
24 surgery?

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1                   A.     Yes.

2                   Q.     Would you agree that smoking  
3     has an impact on stress urinary  
4     incontinence as a result of the constant  
5     coughing, for example?

6                   A.     If one does have a constant  
7     cough, that can certainly be a  
8     predisposing factor for prolapse.

9     Whether or not it affects the surgical  
10   management of stress urinary incontinence  
11   is hard for me to opine on.

12                  I mean, certainly after we  
13   perform slings, we want patients to avoid  
14   heavy lifting for a period of time, so if  
15   you're heavily coughing during that  
16   four-week interval, theoretically it  
17   could create an opportunity for the sling  
18   to move or the repair to be imperfect.

19                  But usually after four  
20   weeks, once a mesh sling is in place, it  
21   doesn't really get affected by coughing,  
22   sneezing, excess pressure, because it's  
23   holding everything in place.

24                  Q.     Would you agree that Ms.

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1       Phillips' smoking history continued to  
2       cause her health issues pre and  
3       post-implant?

4           A.       I mean, I certainly think  
5       it's not a -- healthy to smoke, but it's  
6       hard to quantify or for that matter  
7       directly correlate her smoking with her  
8       health between 2005 and 2016, for  
9       example.

10          Q.       Was she diagnosed with COPD?

11          A.       I think she was.

12          Q.       And I believe she saw her  
13       primary care doctor on numerous occasions  
14       for bronchitis and other upper  
15       respiratory issues; correct?

16          A.       Yes.

17          Q.       And would you agree that  
18       smoking can contribute to those types of  
19       health issues?

20          A.       Yes.

21          Q.       Did you see in the records  
22       where her doctor, Dr. Narula, repeatedly  
23       cautioned her to quit smoking?

24          A.       Yes.

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1 Q. And she refused that advice;  
2 is that correct?

3 MS. SANTRA: Object to form.

4 THE WITNESS: I'm not sure  
5 if she refused the advice, but she  
6 certainly didn't abide by it.

7 MS. STUBBS: Okay. That's  
8 fair.

9 THE WITNESS: Yeah.

10 BY MS. STUBBS:

11 Q. It looks like Ms. Phillips  
12 first presented to Dr. Kim in October of  
13 2004; is that correct?

14 A. Yes.

15 Q. And when she presented, she  
16 had mixed incontinence; correct?

17 A. Primarily stress, but with  
18 some urge incontinence, yes.

19 Q. And that's when he  
20 prescribed the Detrol; correct?

21 A. Yes.

22 Q. And we talked about earlier  
23 how she improved for a period of time,  
24 but then decided to go forward with the

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1 implant for her stress incontinence;  
2 correct?

3 A. Yes.

4 Q. Did you see in the records  
5 where apparently there was a surgery  
6 scheduled to do the TVT and then the  
7 plaintiff wanted to move it up to January  
8 as opposed to March?

9 A. I do recall seeing that,  
10 yes.

11 Q. And, ultimately, that  
12 surgery was performed on January 10th,  
13 2005; correct?

14 A. Yes.

15 Q. Did you see any evidence of  
16 any complications as a result of that  
17 surgery?

18 A. No, I did not.

19 Q. And a cystoscopy was  
20 performed at the time of the implant;  
21 correct?

22 A. Yes.

23 Q. Did you see any evidence of  
24 injury to the bladder or urethra as a

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1 result of that implant?

2 A. I did not.

3 Q. And was she discharged the  
4 same day as the procedure?

5 A. She was.

6 Q. Would you agree that the TVT  
7 implant is a minimally invasive  
8 procedure?

9 A. Correct.

10 MS. STUBBS: I'd like to  
11 look at the operative report for  
12 her implant and I'll mark it as  
13 Exhibit 8.

14 - - -

15 (Deposition Exhibit No.

16 Walmsley (Phillips)-8, 1/10/05  
17 Operative Report for Joanne M.  
18 Phillips, PHILLIPSJ\_UTMC\_MDR00021  
19 through PHILLIPSJ\_UTMC\_MDR00023,  
20 was marked for identification.)

21 - - -

22 BY MS. STUBBS:

23 Q. If you would go with me to  
24 "Operative Indications," please, it

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1 states: "The patient is a 51 year old  
2 lady with significant stress urinary  
3 incontinence"; correct?

4 A. Yes.

5 Q. And would you agree that TVT  
6 at the time it was implanted in Ms.  
7 Phillips was an appropriate device for  
8 treatment of significant stress urinary  
9 incontinence?

10 A. Yes.

11 Q. And then next it states,  
12 "The risks and benefits of transvaginal  
13 tape sling including bleeding, infection,  
14 retention, injury to adjacent organs,  
15 erosion, and anesthesia related  
16 complications were discussed, and she  
17 agrees to proceed"; correct?

18 A. Yes.

19 Q. And after having the TVT  
20 implanted, Ms. Phillips didn't attend her  
21 follow-up appointment in February;  
22 correct?

23 A. That's correct.

24 Q. And she was sent a letter by

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1 Dr. Kim letting her know that she had  
2 missed her appointment, and she didn't go  
3 back to him until 2012; is that correct?

4 A. Yes.

5 Q. However, she did go see her  
6 primary care doctor in between the 2005  
7 implant and 2012, when she returned to  
8 Dr. Kim; correct?

9 A. Yes.

10 Q. Would you agree that the  
11 visits that -- with her primary care  
12 doctor between 2005 following the implant  
13 and 2012 before she goes back to Dr. Kim  
14 -- that the bulk of those visits related  
15 to health issues regarding her poorly  
16 controlled diabetes and her lower back  
17 pain as a result of her motor vehicle  
18 accident?

19 MS. SANTRA: Object to form.

20 That's a large body of records.

21 If you want to show him a few --

22 MS. STUBBS: Sure.

23 I'll mark as Exhibit 9 the  
24 records immediately prior and then

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1 following the implant with her  
2 primary care doctor.

3 - - -

4 (Deposition Exhibit No.

5 Walmsley (Phillips)-9, Twenty  
6 Pages of Medical Records Beginning  
7 with 12/13/05 Visit to Dr. Narula,  
8 PHILLIPSJ\_LAFHC\_MDR00056, was  
9 marked for identification.)

10 - - -

11 BY MS. STUBBS:

12 Q. So the first record is dated  
13 12/13/05. Do you see that?

14 A. I do.

15 Q. And it says she has  
16 occasional pain in her lower back, but no  
17 frequency or dysuria; correct?

18 A. Yes.

19 Q. And she's having pain in her  
20 lower abdomen where the scar was; is that  
21 correct?

22 A. From her recent sling, yes.

23 Q. Would you turn to the next  
24 record, please?

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1                   A.     Yes.

2                   Q.     On this record, she is  
3     reporting pain in her lower back on  
4     external rotation of both hips.

5                   Do you see that?

6                   A.     Yes.

7                   Q.     And she -- those injuries  
8     related to the motor vehicle accident she  
9     had had back in the '90s; correct?

10                  A.     I would assume so, yes.

11                  Q.     She injured her hips in that  
12    accident; correct?

13                  A.     Yes.

14                  Q.     Do you also see where it  
15    says in the first paragraph, "is in total  
16    denial in terms of her blood sugar and  
17    blood pressure control"?

18                  A.     I do see that.

19                  Q.     Would you turn with me until  
20    you get -- I'm sorry. The Bates numbers  
21    are cut off for some reason, but if you  
22    keep going until we get to 7/16/08 --  
23    it's a few more pages. You'll see it at  
24    the top.

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1 A. I'm there.

2 Q. Okay -- this record, it  
3 says, "She is staying nervous and  
4 stressed. She has to watch the grand  
5 kids. Her blood pressure is under fair  
6 control. Her blood sugars are running  
7 high. Her back, legs, and feet hurt.  
8 She says that it is from diabetes. She  
9 does not want to go on insulin. No  
10 abdominal pain, nausea, fever"; correct?

11                    A.        Correct.

12 Q. So up until this point, has  
13 she complained to the -- the one doctor  
14 she was seeing, Dr. Narula, of any  
15 dyspareunia? And take your time to look  
16 at it.

17                   A.     To date, Dr. Narula's  
18 records have no specific language about  
19 dyspareunia in them.

20 Q. What about any reference to  
21 pelvic pain?

22 (Pause.)

23 THE WITNESS: I don't see  
24 any references to pelvic pain thus

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1 far.

2 BY MS. STUBBS:

3 Q. The next record is dated  
4 9/4/08. Do you see that?

5 A. I do.

6 Q. "Patient has cough,  
7 wheezing, sinus drainage. No abdominal  
8 pain, nausea. Her back continues to  
9 hurt. She has had it since her motor  
10 vehicle accident when she was 23 years of  
11 age. Her hips became crooked at that  
12 time. No numbness, tingling, weakness.  
13 Hurts to sit or stand on it for a long  
14 period of time. No abdominal pain."

15 So up until this point, Ms.  
16 Phillips is complaining of pain related  
17 to her motor vehicle accident injuries;  
18 correct?

19 A. Yes.

20 Q. Have you seen any reference  
21 up until this date, 9/4/08, of any  
22 complaints relating to her TVT implant  
23 other than the 12/05 one where she talks  
24 about the scar area hurting?

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1 A. I have not.

2 Q. Would you turn several pages  
3 until you get to 11/3/10?

4 (Pause.)

5 THE WITNESS: Okay.

6 BY MS. STUBBS:

7 Q. On this visit, she's again  
8 complaining of lower back pain; correct?

9 A. Yes.

10 Q. And based on your review of  
11 her records, she had lower back pain as a  
12 result of her motor vehicle accident;  
13 correct?

14 A. In part, yes.

15 Q. What else do you think  
16 contributed to that lower back pain?

17                   A.        I mean, it's such a broad  
18 diagnostic category, low back pain; that  
19 I'm sure a big part of her low back pain  
20 relates to her motor vehicle accident and  
21 even Dr. Narula's medical documentation  
22 speaks to that.

23 You know, that being said,  
24 she may also have additional causes of

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1 low back pain, whether it be arthritis or  
2 things of that nature.

3 Q. Do you in any way believe  
4 her lower back pain was caused by the TTVT  
5 implant?

6 A. I don't.

7 Q. And she was diagnosed with  
8 degenerative arthritis on this visit;  
9 correct?

10 A. Correct.

11 Q. If you would go to the last  
12 visit, it's the last page, 10/24/11, so  
13 this is the year before she goes back to  
14 Dr. Kim; correct?

15 A. Yes.

16 Q. And it says, "The patient  
17 describes pain in both knees and lower  
18 back. Her nerves are shot. She had a  
19 car accident today. No abdominal pain,  
20 change in appetite, weight or fever";  
21 correct?

22 A. Yes.

23 Q. So, again, the year before  
24 she returns to Dr. Kim, she doesn't have

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1 any GYN complaints; correct?

2 MS. SANTRA: Object to form.

3 THE WITNESS: She doesn't  
4 voice any, no.

5 BY MS. STUBBS:

6 Q. And she doesn't have any  
7 abdominal pain based on this record;  
8 correct?

9 A. She doesn't voice any, no.

10 Q. When Ms. Phillips went back  
11 to Dr. Kim, I believe it was -- September  
12 of 2012; correct?

13 A. I thought it was October of  
14 2012.

15 Q. 10/10/12; is that right?

16 A. Correct.

17 Q. -- that was the first visit  
18 she had had with him since the implant;  
19 correct?

20 A. Yes.

21 Q. And she approached Dr. Kim  
22 about wanting the TVT implant out; is  
23 that correct?

24 A. Yes.

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1                   Q.     Were you aware of whether or  
2     not she had filed a lawsuit at that time?

3                   A.     I was not. I am not.

4                   Q.     Have you seen anywhere in  
5     the medical records prior to the visit on  
6     10/10/12 where any doctor recommended  
7     that she have the TVT implant out?

8                   A.     No.

9                   Q.     And have you seen anywhere  
10    in the medical records prior to 10/10/12  
11    where any doctor conducted a pelvic exam?

12                  A.     No.

13                  Q.     And have you seen anywhere  
14    in the medical records prior to 10/10/12  
15    where any doctor noted pelvic pain or  
16    dyspareunia?

17                  A.     Obviously with the exception  
18    of that one visit in December 12th where  
19    she had probably more retropubic, but  
20    nonetheless pelvic pain, no, and no for  
21    dyspareunia either.

22                  Q.     And Dr. Kim noted that he  
23    did not believe the TVT was causing her  
24    problems at that time; is that correct?

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1                   A.     He did make that comment.

2                   Q.     And he suggests that she get  
3     a second opinion; is that right?

4                   A.     Correct.

5                   Q.     And did she ever get that  
6     second opinion?

7                   A.     No.

8                   Q.     And did she ever have a  
9     pelvic exam after that visit?

10                  A.     Not until I saw her.

11                  Q.     Other than the IME. Thank  
12     you.

13                  I'd like to talk now about  
14     your IME. Can you walk me through the  
15     procedure? So from the time the patient,  
16     Ms. Phillips, comes into your office, up  
17     until the end of the exam, what's the  
18     procedure you underwent to perform your  
19     IME?

20                  A.     Certainly. So typically  
21     what would happen and what Ms. Phillips  
22     did is, she presents herself to the  
23     office. There is some paperwork that's  
24     filled out, questions about past medical

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1 history, questions about medications,  
2 questions about current complaints.

3 There is a review of systems form that  
4 the patient fills out.

5 Once those forms are filled  
6 out, she comes back to an examination  
7 room where one of my medical assistants  
8 enters all of the data into the  
9 electronic health record template for her  
10 visit.

11 Once that's completed, then  
12 I will come into the examination room,  
13 introduce myself to the patient, and ask  
14 them questions relating to their  
15 particular complaint.

16 In the case of Mrs.  
17 Phillips, if you go to page 2 of my IME,  
18 you'll see that my history of physical  
19 illness -- or history of present illness,  
20 excuse me -- we call that the HPI, that  
21 in essence is 16 lines long and it is a  
22 memorialization of the patient's  
23 complaints, which in some part are also  
24 predicated on the questions I'm asking

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1 the patient.

10 They'll cover -- they'll take their  
11 clothes off from the waist down, cover  
12 themselves with a drape. I step out of  
13 the room during this process and then  
14 come back in the room with a female  
15 chaperone to examine the patient.

16 My examination is a  
17 comprehensive examination. I exam their  
18 heart, lungs, abdomen, back, skin. When  
19 I do the pelvic exam, in addition to  
20 doing a pelvic exam, I occasionally will  
21 scan the bladder. If there's a question  
22 of incomplete emptying, I'll do that --  
23 in Ms. Phillips' case, I did -- and then  
24 I'll perform a complete pelvic exam,

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1 after which time, I go to my office,  
2 record the physical exam findings, and  
3 then finish the office visit with the  
4 patient coming to my office.

5 It's a little bit of a  
6 nuance in the IME world because I'm not a  
7 treating physician, so I'm not  
8 necessarily going to engage the patient  
9 in treatment, but I will discuss with the  
10 patient my conclusions, and that's what I  
11 did with Ms. Phillips.

12 Q. You indicated you did do a  
13 bladder scan; is that correct?

14 A. I did.

15 Q. Did you see any evidence of  
16 incomplete emptying?

17 A. Her postvoid residual was 32  
18 milliliters, which is fairly low.

19 Q. You mentioned some intake  
20 forms --

21 A. Yes.

22 Q. -- is that something --  
23 Hayleigh, do you all have those or --

24 MS. SANTRA: I don't think

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1                   we've gotten those.

2                   THE WITNESS: Typically what  
3                   happens with the intake forms is,  
4                   once the data is entered, they're  
5                   shredded.

6                   MS. STUBBS: Will you all  
7                   just check on that -- if you don't  
8                   have them, fine. If you do, will  
9                   you give them to counsel?

10                  THE WITNESS: Sure.

11                  MS. STUBBS: Okay.

12                  BY MS. STUBBS:

13                  Q.        Let's turn to the second  
14                  page of your IME. Let's start with  
15                  social history. Under "Smoking Status,"  
16                  it says, "Unknown if ever smoked."

17                  Would you agree based on  
18                  your review now of her records that she  
19                  was a smoker?

20                  A.        Yes.

21                  Q.        And then "History of Present  
22                  Illness," I want to talk about where  
23                  she's -- is this based on what she's  
24                  telling you about her symptoms or your

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1       nurse?

2           A.     No, no.

3           Q.     It's you?

4           A.     It's me asking her questions  
5        and her responding to my questions.

6           Q.     Do you see where it says,  
7        "developed pain shortly thereafter"?

8           A.     Yes.

9           Q.     And that's after her TTV  
10       implant; correct?

11       A.     Correct.

12       Q.     And then it says, "had some  
13       vaginal bleeding on and off for six  
14       months"; is that correct?

15       A.     Yes.

16       Q.     Did you see anywhere in the  
17       medical records where she reported pain  
18       or vaginal bleeding after having the TTV  
19       implanted?

20       A.     Well, firstly, when she saw  
21       her primary care doctor in December of  
22       2005, there was some pain in the area of  
23       her incisions from her TTV.

24               With regards to pelvic pain,

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1 I didn't see any record of that  
2 thereafter, but obviously she has other  
3 sources of pain that she did complain  
4 about afterwards.

5 Q. What about vaginal bleeding?

6 A. I don't recall seeing that.

7 Q. And it looks like after 18  
8 months, she started developing MUI. Is  
9 that mixed urinary incontinence?

10 A. Correct.

11 Q. And that would be stress and  
12 urge; correct?

13 A. Yes.

14 Q. So the urge incontinence  
15 that had gotten better on Detrol came  
16 back after having the TVT implant; is  
17 that correct?

18 A. Yes.

19 MS. SANTRA: Object to form.

20 BY MS. STUBBS:

21 Q. And would you agree that TVT  
22 is not indicated to treat urge?

23 A. It's not indicated to treat  
24 urge.

Konstantin Walmsley, M.D.

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1 Q. And then it says, "After  
2 about 1 year, she started developing  
3 pelvic pain. She also had dyspareunia,  
4 as she was sexually active with her  
5 husband for several years (till 2009)."

6 Based on my deposition of  
7 plaintiff, would you agree that she  
8 stated on the record that she only had  
9 sex one time after the implant?

10 MS. SANTRA: I have that  
11 deposition if --

12 THE WITNESS: I have it  
13 right here, actually.

14 (Pause.)

15 THE WITNESS: Yes, one time.  
16 BY MS. STUBBS:

17 Q. And she did note to you that  
18 she had had some mild discomfort with  
19 intercourse prior to having the TVT;  
20 correct? That's what's reflected. It  
21 says, "She had some mild discomfort with  
22 intimacy before surgery but this was much  
23 worse"; is that correct?

24 A. Correct, yes.

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1 Q. And then it says, "She  
2 describes a rough, tearing sensation to  
3 sex especially upon entering the vagina."

4 A. Right.

5 Q. Did you see anywhere in the  
6 medical records where anything of that  
7 nature was mentioned to any of her  
8 treating physicians following the TVT  
9 implant?

10 A. I did not.

11 Q. You also note a history of  
12 two to three UTIs a month. Did you see  
13 anywhere in the medical records where  
14 that was indicated?

15 A. I did not.

16 Q. Did you see any evidence of  
17 a urinary tract infection upon your  
18 examination?

19 A. No.

20 Q. And you saw no erosion or  
21 extrusion; correct?

22 A. I did not.

23 Q. And when you were able to --  
24 when you noted tenderness upon your exam,

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1 was that at the site of where the mesh  
2 was located?

3 A. Yes.

4 Q. Did you see any evidence of  
5 where Ms. Phillips went back to Dr. Kim  
6 after the 10/10/12 visit?

7 A. I don't believe so.

8 Q. Did you see any evidence  
9 where she saw any urogynecologist,  
10 gynecologist, or urologist after  
11 10/10/12, other than your IME?

12 A. No.

13 Q. And so you performed a  
14 pelvic exam; correct?

15 A. Yes.

16 Q. And you took your -- did  
17 your do a urinalysis as well?

18 A. A urine analysis?

19 Q. Yes.

20 A. Yes.

21 Q. And you did a bladder scan;  
22 correct?

23 A. Yes.

24 Q. Any other testing or exams

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1 that you performed at that time on her  
2 female anatomy?

3 A. No, ma'am.

4 Q. Did she report any bowel  
5 problems to you during her IME?

6 A. Yes.

7 Q. What are those?

8 A. She noted that she had some  
9 constipation.

10 Q. Is it your opinion that that  
11 constipation is related to the mesh?

12 A. No.

13 Q. Do you have an opinion as to  
14 what the cause of her constipation is?

15 A. Not specifically, I don't.

16 Q. Have we discussed all of  
17 your opinions to date during this  
18 deposition today?

19 MS. SANTRA: Object to form.

20 THE WITNESS: I believe so,  
21 yes.

22 MS. STUBBS: I don't have  
23 any further questions, Hayleigh.

24 Do you?

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1 MS. SANTRA: Okay. I'm  
2 going to, but I -- is it okay if I  
3 go to the bathroom real quick?

4 MS. STUBBS: Of course.  
5 We'll go off the record.

6 (A recess was taken from  
7 2:02 p.m. to 2:06 p.m.)

8 - - -

9 EXAMINATION

10 - - -

11 BY MS. SANTRA:

12 Q. Dr. Walmsley, you performed  
13 a differential diagnosis when coming to  
14 your opinions about Ms. Phillips;  
15 correct?

16 A. I did.

17 Q. And your opinions that  
18 you've expressed about Ms. Phillips are  
19 based on your clinical experience, your  
20 review of her medical records, your  
21 independent examination of Ms. Phillips,  
22 and your knowledge of the medical  
23 literature; is that right?

24 A. Correct.

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1 Q. And when you were performing  
2 your differential diagnosis for Ms.  
3 Phillips, did you take into account all  
4 of her other medical conditions,  
5 including diabetes, smoking, the hip and  
6 back pain from her motor vehicle accident  
7 in the 1990s, her abdominal hysterectomy,  
8 her appendectomy, tumor removals from her  
9 neck, her COPD, hypertension, arthritis,  
10 GERD, and hyperlipidemia?

11 MS. STUBBS: Object to form.

12 THE WITNESS: Yes.

13 BY MS. SANTRA:

14 Q. And is it -- based on your  
15 differential diagnosis, is it your  
16 opinion that the TVT sling is a  
17 substantial factor in the pain that you  
18 palpated upon examination?

19 A. Yes.

20 MS. STUBBS: Object to form.

21 BY MS. SANTRA:

22 Q. And how did you rule out Ms.  
23 Phillips' hysterectomy as a cause for  
24 that pain that you observed upon

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1 examination?

2 A. Well, I mean, first off, her  
3 hysterectomy was performed over 20 years  
4 ago and, generally speaking, if one  
5 encounters pelvic pain or dyspareunia  
6 from a procedure such as a hysterectomy,  
7 you would expect that that would be  
8 present soon after the hysterectomy and  
9 certainly a chronic condition that's  
10 commented on in the medical records. I  
11 mean, she had no comment made as to that  
12 being the case in the medical records  
13 that I reviewed.

14 In addition, at least on  
15 physical examination, when I examined Ms.  
16 Phillips, she had no tenderness at the  
17 apex of the vagina, which is typically  
18 where one encounters pelvic pain after a  
19 hysterectomy.

20 Q. In your case-specific  
21 opinions, you mention the scar plate  
22 formation that you saw that was due to  
23 the TVT sling; is that right?

24 A. Yes.

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1 Q. And is that scar plate  
2 formation that you -- that was painful  
3 for Ms. Phillips when you examined her,  
4 is that evidence of her foreign body  
5 reaction to the sling?

6 A. That's correct.

7 Q. And you talked about lichen  
8 sclerosus and vaginal atrophy; is that  
9 correct?

10 A. I did, yes.

11 Q. And Ms. Phillips has those  
12 conditions as well?

13 A. Yes, she has evidence of  
14 both of those conditions.

15 Q. Even given those conditions,  
16 is the TVT -- excuse me. Strike that.

17 Even given her lichen  
18 sclerosus and vaginal atrophy, is the TVT  
19 sling still a substantial factor in  
20 producing the pain that you reproduced  
21 upon examination?

22 MS. STUBBS: Object to form.

23 THE WITNESS: Yes.

24 BY MS. SANTRA:

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1                   Q.     I want to talk about your  
2     reliance list for a minute. In your  
3     reliance list, you say that you  
4     incorporated Dr. Blaivas' general TVT  
5     causation report; is that correct?

6                   A.     Not as specifically as you  
7     just stated, but, yes, I did rely upon  
8     Dr. Blaivas' report for general opinions.

9                   Q.     And so before writing your  
10    report for Ms. Phillips, you had reviewed  
11    Dr. Blaivas' general causation report on  
12    the TVT?

13                  A.     Yes.

14                  Q.     And to the extent Dr.  
15    Blaivas relied on Ethicon internal  
16    documents or other materials that he  
17    cites in his report, you would  
18    incorporate all of that into your -- part  
19    of your -- or all of Dr. Blaivas'  
20    conclusions from his review of those  
21    documents into your knowledge base; is  
22    that correct?

23                  MS. STUBBS: Object to form.

24                  MS. SANTRA: I don't know if

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1 I need to ask that again.

2 THE WITNESS: Well, I think  
3 to answer your question, I didn't  
4 specifically review Ethicon  
5 internal documents myself relating  
6 to this case.

7 Obviously having read and  
8 reviewed Dr. Blaivas' report,  
9 which certainly does reflect his  
10 review of those internal  
11 documents, what I can tell you is,  
12 having trained under Dr. Blaivas  
13 and knowing his reputation as a  
14 key opinion leader in the field of  
15 urology and the management of  
16 incontinence in both men and  
17 women, I would trust and rely on  
18 his opinion -- you know, on his  
19 interpretation of those documents  
20 and records.

21 BY MS. SANTRA:

22 Q. And I believe you mentioned  
23 the fact that the TVT IFU in 2005 did not  
24 have dyspareunia or chronic pain as some

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1 of the adverse events; is that correct?

2 A. Yes.

3 Q. And the 2015 TVT IFU does  
4 list dyspareunia and chronic pain as  
5 potential adverse events; is that  
6 correct?

7 MS. STUBBS: Object to the  
8 form.

9 THE WITNESS: Amongst other  
10 potential adverse events, yes.

11 BY MS. SANTRA:

12 Q. So even according to  
13 Ethicon, the TVT can cause chronic pain  
14 and dyspareunia; correct?

15 MS. STUBBS: Object to the  
16 form.

17 THE WITNESS: That's  
18 correct.

19 BY MS. SANTRA:

20 Q. You were asked some  
21 questions about -- some questions  
22 comparing an autologous sling to the TVT  
23 mesh device. Do you remember those  
24 questions?

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1                   A.     I do.

2                   Q.     And I think you were asked  
3 generally whether an autologous sling can  
4 cause dyspareunia or pelvic pain. Do you  
5 remember that question?

6                   A.     I do.

7                   Q.     Is there a difference in the  
8 characteristic and nature of any  
9 dyspareunia or pelvic pain that's caused  
10 by an autologous sling versus the nature  
11 and characteristic of dyspareunia or  
12 pelvic pain caused by a mesh device?

13                   MS. STUBBS: Object to the  
14 form.

15                   THE WITNESS: Yes.

16 BY MS. SANTRA:

17                   Q.     What are some of the  
18 differences?

19                   A.     So using an autologous  
20 fascial sling as compared to synthetic  
21 mesh creates a different host response.  
22 When using mesh in the pelvic arena,  
23 there is an inflammatory response that  
24 tends to generate more scarring and

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1 fibrosis and more inflammation, which  
2 tends to lead towards more significant  
3 dyspareunia and pelvic pain, not only  
4 with regards to intensity of the pain,  
5 but chronicity of the pain.

6 Autologous facial slings can  
7 create or have these adverse events as  
8 well. It's part of the informed consent  
9 process for autologous facial slings.  
10 However, the nature of the pain and the  
11 nature of the dyspareunia, both  
12 quantitatively and qualitatively are  
13 different because the inflammatory  
14 response, that response which can create  
15 fibrosis and scarring, is much less  
16 intense and less significant than what is  
17 seen with synthetic mesh.

18 One of the reasons you need  
19 to suture an autologous fascial sling in  
20 place, for example, is because unlike  
21 synthetic mesh, where the fibrosis and  
22 scarring essentially sets that mesh in  
23 place, fairly quickly, with autologous  
24 facial slings, that type of vigorous

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1 inflammatory response is essentially  
2 absent such that if you were to place an  
3 autologous fascial sling and not stitch  
4 it into location, it would have a very  
5 high rate of migration and failure  
6 because it wasn't -- it wouldn't position  
7 itself under the urethra in such a way as  
8 to create support effectively.

9 Q. In regards to Exhibit 7,  
10 which is the AUGS and SUFU statement that  
11 we -- that defense counsel went over --

12 A. Yes.

13 Q. -- have you seen that  
14 statement before?

15 A. I have.

16 Q. And does anything in that  
17 statement change your opinions today  
18 about Ms. Phillips?

19 A. No.

20 Q. And defense counsel asked  
21 you questions to the effect of that the  
22 IFU is just one source of information for  
23 doctors; is that correct?

24 A. I remember that question,

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1 yes.

2 Q. And you said that you rely  
3 heavily on IFUs for your practice?

4 A. I do.

5 Q. Can you explain that a  
6 little bit?

7 A. I can.

8 There's no question that  
9 gaining experience and knowledge with  
10 procedures, other than on a personal  
11 level, can be augmented by research and  
12 review; and inasmuch as some of that  
13 review can be related to peer-reviewed  
14 literature, can be related to published  
15 guidelines, can be related to opinions  
16 shared by key opinion leaders or  
17 colleagues, to my mind, the framework of  
18 knowledge, whether it's a package insert  
19 for a medication, for example, or an IFU  
20 for a medical device is -- the  
21 foundation, I should say, really are  
22 those types of products in my practice.

23 I believe that the IFU  
24 serves as a guide for literature, for

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1     opinions put forth by national leaders in  
2     fields such as incontinence; and to some  
3     degree, if the IFU is incomplete, the  
4     literature is incomplete, the opinions  
5     put forth by key opinion leaders are  
6     incomplete because these very -- these  
7     very authors, these very surgeons -- the  
8     literature that even in my reliance list  
9     is to some degree premised on information  
10    in package inserts and IFUs, for example.

11           Q.     And that would be kind of  
12    especially true when a product is in the  
13    first few years of a product being on the  
14    market; is that right?

15           MS. STUBBS:   Object to the  
16    form.

17           THE WITNESS:   To some  
18    extent, I think that's when the  
19    IFU is the most critically  
20    important, because that's really  
21    setting the foundation for how you  
22    want to incorporate the use of a  
23    medical device in your practice.

24    BY MS. SANTRA:

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1                   Q.     Counsel asked you some  
2     questions about whether in every report  
3     you've written, you found that the TVT  
4     was a cause for the plaintiff's injuries.

5                   Do you remember that line of  
6     questioning?

7                   A.     I remember some questioning  
8     regarding IFU commentary.

9                   Q.     And for the TVT, that IFU  
10    wasn't changed in any substantial way  
11    until 2015; is that correct?

12                  MS. STUBBS: Object to the  
13    form.

14                  THE WITNESS: Yes, it is.

15    BY MS. SANTRA:

16                  Q.     So from 2000 to 2015, when  
17    it was substantially changed, there was  
18    basically the same information in the TVT  
19    IFU; correct?

20                  MS. STUBBS: Objection to  
21    form.

22                  THE WITNESS: Essentially,  
23    yes.

24    BY MS. SANTRA:

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1 Q. Have you rendered all your  
2 opinions to a reasonable degree of  
3 medical certainty?

4 A. I have, yes.

5 MS. SANTRA: I think that is  
6 all I have for you.

7 MS. STUBBS: I don't have  
8 any further questions.

9 (Witness excused.)

10 (Deposition concluded at  
11 approximately 2:23 p.m.)

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Konstantin Walmsley, M.D.

1

2 CERTIFICATE

3

4

5 I HEREBY CERTIFY that the  
6 witness was duly sworn by me and that the  
7 deposition is a true record of the  
8 testimony given by the witness.

9

10 It was requested before  
11 completion of the deposition that the  
12 witness, KONSTANTIN WALMSLEY, M.D., have  
13 the opportunity to read and sign the  
14 deposition transcript.

15

16

17

18

Kimberly A. Cahill  
19 KIMBERLY A. CAHILL, a  
20 Federally Approved Registered  
21 Merit Reporter and Notary Public

22

Dated: August 22, 2016

23

24

(The foregoing certification  
of this transcript does not apply to any  
reproduction of the same by any means,  
unless under the direct control and/or  
supervision of the certifying reporter.)

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1                   INSTRUCTIONS TO WITNESS

2

3                   Please read your deposition  
4    over carefully and make any necessary  
5    corrections. You should state the reason  
6    in the appropriate space on the errata  
7    sheet for any corrections that are made.

8                   After doing so, please sign  
9    the errata sheet and date it.

10                  You are signing same subject  
11    to the changes you have noted on the  
12    errata sheet, which will be attached to  
13    your deposition.

14                  It is imperative that you  
15    return the original errata sheet to the  
16    deposing attorney within thirty (30) days  
17    of receipt of the deposition transcript  
18    by you. If you fail to do so, the  
19    deposition transcript may be deemed to be  
20    accurate and may be used in court.

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E R R A T A  
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4 PAGE LINE CHANGE

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6 REASON: \_\_\_\_\_

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24 REASON: \_\_\_\_\_

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1

2 ACKNOWLEDGMENT OF DEPONENT

3

4 I, \_\_\_\_\_, do  
5 hereby certify that I have read the  
6 foregoing pages, 1 - 106, and that the  
7 same is a correct transcription of the  
8 answers given by me to the questions  
9 therein propounded, except for the  
10 corrections or changes in form or  
11 substance, if any, noted in the attached  
12 Errata Sheet.

13

14

15

16 \_\_\_\_\_ KONSTANTIN WALMSLEY, M.D. DATE

17

18

19 Subscribed and sworn  
to before me this

20 \_\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_.

21 My commission expires: \_\_\_\_\_

22

23 \_\_\_\_\_ Notary Public

24

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1

LAWYER'S NOTES

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